

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Withdrawn) A system for establishing vascular access over a guidewire, said system comprising:

a dilator having a lumen sized to be introduced over a guidewire having a pre-selected diameter; and

a radially expandable sleeve having a lumen therethrough and an unexpanded diameter, said sleeve being configured to expand to a larger diameter as the dilator is advanced through the lumen of the sleeve.

2. (Withdrawn) A system as in claim 1, wherein the dilator is tapered at one end to facilitate advancement through the lumen of the radially expandable sleeve.

3. (Withdrawn) A system as in claim 2, wherein the dilator comprises an outer tube and an inner obturator, wherein the obturator has the guidewire lumen and the tapered end and wherein the obturator is removable from the outer tube so that the tube may be left in place within the radially expandable sleeve after expansion.

4. (Withdrawn) A system as in claim 1, wherein the radially expandable sleeve has a compliant or elastic structure so that its cross-section will collapse after expansion if the dilator is withdrawn from the lumen of the sleeve.

5. (Withdrawn) A system as in claim 4, wherein the radially expandable sleeve comprises a tubular braid.

6. (Withdrawn) A system as in claim 5, wherein the tubular braid is a mesh of non-elastic filaments wherein radial expansion causes axial shortening of the braid.

7. (Withdrawn) A system as in claim 6, wherein the braid is embedded in or covered by an elastic layer.

8. (Withdrawn) A system as in claim 1, wherein the radially expandable sleeve is plastically deformable or has a locking structure so that it retains its expanded diameter after the dilator is withdrawn from the lumen of the sleeve.

9. (Withdrawn) A system as in claim 1, wherein the radially expandable sleeve comprises an anti-thrombotic coating.

10. (Withdrawn) A system as in claim 1, further comprising a guidewire.

11. (Withdrawn) A system as in claim 1, further comprising a sleeve introducer having a tapered distal end and a lumen therethrough, said sleeve introduced being configured to receive a guidewire through its lumen and to be received within the lumen of the sleeve, whereby an assembly of the sleeve and sleeve introducer can be formed so that the tapered end of the sleeve introducer can be advanced through the tissue to facilitate entry.

12. (Withdrawn) A system as in claim 11, wherein the guidewire has a nominal diameter of 0.89 mm (0.035 in), the dilator has a lumen diameter of 1 mm (0.4 in.), and the sleeve has a lumen diameter prior to expansion of 0.96 mm (0.038 in.).

13. (Withdrawn) A system as in claim 12, wherein the dilator has an outside diameter in the range from 1.3 mm to 3.3 mm.

14. (Withdrawn) A system as in claim 11, wherein the guidewire has a nominal diameter of 0.36 mm (0.014 in.), the dilator has a lumen diameter of 0.46 mm (0.018 in.), and the sleeve has a lumen diameter prior to expansion of 0.41 mm (0.016 in.).

15. (Withdrawn) A system as in claim 14, wherein the dilator has an outside diameter in the range from 1 mm to 2.5 mm.

16. (Currently Amended) A method for establishing vascular access, said method comprising:

forming a percutaneous tissue tract to a target blood vessel;

positioning a guidewire through the tissue tract;

positioning a radially expandable sleeve over the guidewire and through the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue tract, wherein the expandable sleeve is in a narrow diameter configuration; and

inserting [[the]] a dilator into the radially expandable sleeve to radially expand the expandable sleeve to a larger diameter configuration to provide an access lumen to the blood vessel.

17. (Original) A method as in claim 16, wherein forming the percutaneous tissue tract comprises penetrating a needle through tissue overlying the target blood vessel, passing the guidewire through the needle, and removing the needle from over the guidewire.

18. (Original) A method as in claim 16, wherein positioning the radially expandable sleeve comprises advancing a sleeve having an outer diameter which is no more than 300% of the outer diameter of the guidewire.

19. (Original) A method as in claim 16, wherein the radially expandable sleeve has a compliant or elastic structure so that its cross-section will collapse after expansion.

Claims 20-21 (Canceled)

22. (Previously Presented) A method as in claim 16, wherein the braid is embedded in or covered by an elastic layer.

23. (Original) A method as in claim 16, wherein the radially expandable sleeve is plastically deformable or has a locking structure so that it retains its expanded diameter.

24. (Original) A method as in claim 16, wherein the radially expandable sleeve comprises an anti-thrombotic coating.

25. (Original) A method as in claim 24, wherein the radially expandable sleeve is positioned by advancing the sleeve behind a tapered distal tip.

26. (Original) A method as in claim 16, wherein the guidewire has a nominal diameter of 0.89 mm (0.035 in.), the dilator has a lumen diameter of 1 mm (0.4 in.), and the sleeve has a lumen diameter prior to expansion of 0.96 mm (0.038 in.).

27. (Original) A method as in claim 26, wherein the dilator has an outside diameter in the range from 1.3 mm to 3.3 mm.

28. (Original) A method as in claim 16, wherein the guidewire has a nominal diameter of 0.36 mm (0.014 in.), the dilator has a lumen diameter of 0.46 mm (0.018 in.), and the sleeve has a lumen diameter prior to expansion of 0.41 mm (0.016 in.).

29. (Original) A method as in claim 28, wherein the dilator has an outside diameter in the range from 1 mm to 2.5 mm.

30. (Previously Presented) A method for establishing vascular access, said method comprising:

forming a percutaneous tissue tract to a target blood vessel;

positioning a guidewire through the tissue tract;

positioning a radially expandable sleeve over the guidewire and through the tissue tract with a distal end in the blood vessel and a proximal end outside the tissue tract, wherein the expandable sleeve is in a narrow diameter configuration, wherein the radially expandable sleeve comprises a tubular braid formed of a mesh of non-elastic filaments which axially shorten the braid upon radial expansion thereof;

introducing a dilator over the guidewire and through the expandable sleeve to increase the diameter of the expandable sleeve to a larger diameter; and

removing the dilator wherein the expandable sleeve retains the larger diameter.

31. (Original) A method as in claim 30, wherein forming the percutaneous tissue tract comprises penetrating a needle through tissue overlying the target blood vessel, passing the guidewire through the needle, and removing the needle from over the guidewire.

32. (Original) A method as in claim 30, wherein positioning the radially expandable sleeve comprises advancing a sleeve having an outer diameter which is no more than 300% of the outer diameter of the guidewire.

33. (Original) A method as in claim 30, wherein the radially expandable sleeve has a compliant or elastic structure, wherein the large diameter of the sleeve is maintained by an outer tube of the dilator which remains in place after the dilator is removed.

Claims 34-35 (Canceled)

36. (Previously Presented) A method as in claim 30, wherein the braid is embedded in or covered by an elastic layer.

37. (Original) A method as in claim 30, wherein the radially expandable sleeve is plastically deformable or has a locking structure so that it retains its larger diameter after the dilator is withdrawn from the lumen of the sleeve.

38. (Original) A method as in claim 30, wherein the radially expandable sleeve comprises an anti-thrombotic coating.

39. (Original) A method as in claim 38, wherein the radially expandable sleeve is positioned by advancing the sleeve behind a tapered distal tip.

40. (Original) A method as in claim 30, wherein the guidewire has a nominal diameter of 0.89 mm (0.035 in.), the dilator has a lumen diameter of 1 mm (0.4 in.), and the sleeve has a lumen diameter prior to expansion of 0.96 mm (0.038 in.).

41. (Original) A method as in claim 40, wherein the dilator has an outside diameter in the range from 1.3 mm to 3.3 mm.

42. (Original) A method as in claim 30, wherein the guidewire has a nominal diameter of 0.36 mm (0.014 in.), the dilator has a lumen diameter of 0.46 mm (0.018 in.), and the sleeve has a lumen diameter prior to expansion of 0.41 mm (0.016 in.).

43. (Original) A method as in claim 42, wherein the dilator has an outside diameter in the range from 1 mm to 2.5 mm.

44. (Previously Presented) An improved method for establishing vascular access, said method being of the type wherein a tapered dilator is introduced over a guide wire to enlarge a percutaneous tissue tract, wherein the improvement comprises introducing a radially expandable sleeve over the guidewire prior to introducing the dilator, wherein the radial expandable sleeve comprises a tubular braid formed of a mesh of non-elastic filaments which axially shorten the braid upon radial expansion thereof, and thereafter introducing the dilator over the guidewire and through the sleeve, whereby axial forces on the tissue from the dilator are reduced.

45. (Withdrawn) A kit comprising:
a radially expandable sleeve having a lumen therethrough and an unexpanded diameter, said sleeve being configured to be introduced over a guidewire and expand to a larger diameter as a dilator is advanced through the lumen; and
instructions for use according to claim 44.

46. (Withdrawn) A kit as in claim 45, further comprising a dilator having a lumen sized to be introduced over the guidewire.

47. (Withdrawn) A kit as in claim 46, further comprising the guidewire.

48. (Withdrawn) A kit as in claim 46, further comprising a sleeve introducer having a tapered distal end and a lumen therethrough, said sleeve introduced being configured to receive a guidewire through its lumen and to be received within the lumen of the sleeve, whereby an assembly of the sleeve and sleeve introducer can be formed so that the tapered end of the sleeve introducer can be advanced through the tissue to facilitate entry.

49. (Withdrawn) A kit as in claim 46, further comprising a needle.

50. (Withdrawn) A kit as in claim 46, further comprising a package wherein the sleeve, dilator, and guidewire are contained in the package in a sterile condition.